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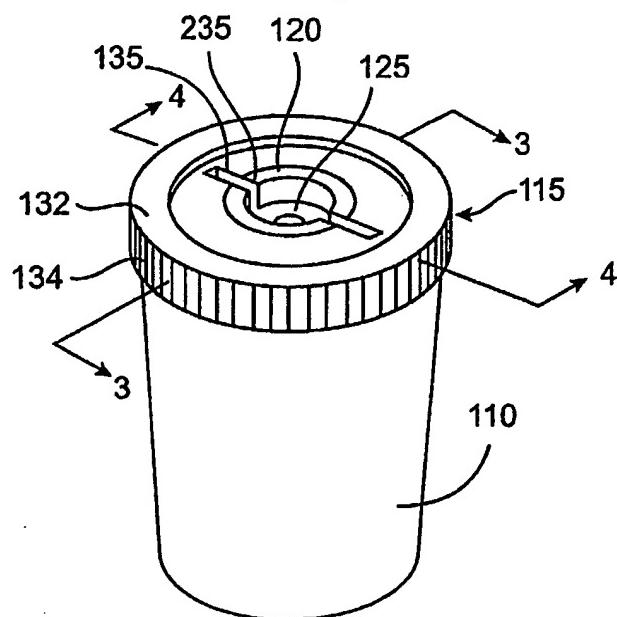
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(54) Title: BIOLOGICAL SPECIMEN COLLECTION AND ANALYSIS SYSTEM



(57) Abstract: Disclosed is a device for collecting a fluid specimen. The device comprises a container that can receive a fluid specimen; a plunger movably positioned within the container, wherein the plunger can move from an initial position at an upper region of the container to a secondary position below the first position; a fluid segregation chamber that can receive a portion of the fluid specimen from the container, wherein any fluid in the segregation chamber is segregated from the fluid specimen in the container; a fluid flow lumen that provides a passageway for at least a portion of the fluid specimen to flow into the fluid segregation chamber, wherein a first end of the passageway has a first opening that opens into the fluid segregation chamber and a second end of the passageway has a second opening that can receive at least a portion of the fluid specimen; and a seal member that covers the first opening or the second opening to prevent fluid from flowing therethrough. A test element can be used to push the plunger from the initial position toward the secondary position to break the seal member and cause at least a portion of the fluid specimen to flow through the second opening into the fluid flow lumen and into the fluid segregation chamber through the first opening.

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BIOLOGICAL SPECIMEN COLLECTION AND ANALYSIS SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 This invention relates generally to specimen collection devices and, more particularly, to a system that can be used to isolate and analyze a portion of a collected fluid specimen.

2. Description of the Related Art

It is often desirable to perform one or more tests on a bodily fluid 10 specimen, such as to detect the presence of an illegal drug substance or a pregnancy indicator. The fluid specimen is commonly collected in a container, which is then closed and transported to a test center. A human operator then opens the container and exposes at least a portion of the fluid specimen to a test element, such as a test card, that can detect the presence 15 or absence of a substance in the fluid specimen.

It is known that bodily fluid specimens can be infectious. Consequently, when the fluid specimen is being tested, it is desirable to isolate the portion of the specimen being tested from the human operator and from the general environment. One reason for this is to reduce the likelihood 20 of the fluid specimen contaminating the general environment and to also reduce the likelihood of the human operator being contaminated. Another reason is to reduce the likelihood that the human operator or the general environment will contaminate the fluid specimen and introduce an inaccuracy in the testing of the fluid specimen.

In certain circumstances, it can also be desirable to conduct a test on just a portion of the fluid specimen and to leave the remaining, untested portion of the fluid specimen in an undisturbed state. In such cases, one primary concern is that the portion of the fluid specimen being tested does not 5 contaminate the remaining, untested portion of the fluid specimen. Thus, it is desirable that the collection apparatus provide a means for segregating a portion of the fluid specimen so that the separated portion does not have any contact with the remainder of the fluid specimen.

In view of the foregoing, there is a need for a fluid specimen collection 10 system that permits collection of a fluid specimen in a secure manner so as to reduce the risk of contamination and that also permits a portion of the fluid specimen to be segregated in an easy manner.

SUMMARY

Disclosed is a device for collecting a fluid specimen. The device 15 comprises a container that can receive a fluid specimen; a plunger movably positioned within the container, wherein the plunger can move from an initial position at an upper region of the container to a secondary position below the first position; a fluid segregation chamber that can receive a portion of the fluid specimen from the container, wherein any fluid in the segregation 20 chamber is segregated from the fluid specimen in the container; a fluid flow lumen that provides a passageway for at least a portion of the fluid specimen to flow into the fluid segregation chamber, wherein a first end of the passageway has a first opening that opens into the fluid segregation chamber and a second end of the passageway has a second opening that can receive

at least a portion of the fluid specimen; and a seal member that covers the first opening or the second opening to prevent fluid from flowing therethrough. A test element can be used to push the plunger from the initial position toward the secondary position to break the seal member and cause at least a 5 portion of the fluid specimen to flow through the second opening into the fluid flow lumen and into the fluid segregation chamber through the first opening.

Also disclosed is a method of analyzing a fluid specimen. The method comprises providing a container that contains the fluid specimen, the container including a fluid segregation chamber that can segregate at least a 10 first portion of the fluid specimen from a second portion of the fluid specimen, wherein a fluid flow lumen provides a fluid passageway for a portion of the fluid specimen to flow from the container into the fluid segregation chamber, the fluid flow lumen having a seal that prevents fluid from flowing into the fluid flow lumen; and inserting a test element into the container so that the seal is 15 punctured and the test element depresses a plunger to cause at least a portion of fluid in the container to flow into the fluid flow lumen and into the fluid segregation chamber, wherein at least a portion of the test element moves into the fluid segregation chamber in contact with the portion of the fluid specimen in the fluid segregation chamber.

20 Also disclosed is a device for collecting a fluid specimen. The device comprises a container that defines a main chamber that can receive a fluid specimen; a fluid segregation chamber coupled to the container for segregating at least a portion of the fluid specimen from the main chamber; a fluid flow lumen that provides a passageway for fluid to flow into the fluid

segregation chamber from the main chamber, the fluid flow lumen having an upper opening that opens into the segregation chamber; a seal that covers the upper opening of the fluid flow lumen to prevent fluid from flowing through the upper opening; and a plunger coupled to the container, wherein 5 the plunger can be moved in a downward direction to force at least a portion of the fluid specimen to flow into the fluid flow lumen toward the fluid segregation chamber, wherein the seal must be broken in order for the plunger to be moved in a downward direction.

Other features and advantages of the present invention should be 10 apparent from the following description of various embodiments, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a specimen collection system of the present invention in an assembled state.

15 Figure 2 is a perspective view of the specimen collection system in an exploded state.

Figure 3 is a cross-sectional view of the assembled specimen collection system along line 3-3 of Figure 1.

20 Figure 4 is a cross-sectional view of the assembled specimen collection system along line 4-4 of Figure 1.

Figure 5 is a cross-sectional view of the assembled specimen collection system, which is shown containing a biological specimen.

Figure 6 is a cross-sectional view of the assembled specimen collection system containing a specimen and with a test card preparing to actuate the system.

Figure 7 is another cross-sectional view of the assembled specimen collection system, the section view in Figure 7 taken 90° from the section view of Figure 6.

Figure 8 is a cross-sectional view of the assembled specimen collection system with the test card actuating the system to cause a portion of the specimen to flow into a fluid segregation chamber.

Figure 9 is a cross-sectional view of the assembled specimen collection system with the test card in a test position.

Figure 10 is another cross-sectional view of the assembled specimen collection system with the test card in a test position as shown in Figure 9, the section view in Figure 10 taken 90° from the section view of Figure 9.

Figure 11 is a perspective view of a second embodiment of the specimen collection system.

Figure 12 is an exploded view of the specimen collection system of Figure 11.

Figure 13 is a cross-sectional view of the specimen collection system of Figure 11.

Figure 14 is a cross-sectional view of the specimen collection system of Figure 11.

Figures 15-17 show various steps involved with using the specimen collection system.

DETAILED DESCRIPTION

DEFINITIONS

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in
5 the art to which this invention belongs.

“Assaying” denotes testing for or detecting the presence of a substance or material, such as, but not limited to, a chemical, an organic compound, an inorganic compound, a metabolic product, a drug or a drug metabolite, an organism or a metabolite of such an organism, a nucleic acid,
10 a protein, or a combination thereof. Optionally, assaying denotes measuring the amount of the substance or material. Assaying further denotes an immunological test, a chemical test, an enzymatic test, and the like.

“Sample” or “specimen” may be used interchangeably. “Sample” or “specimen” denotes any material to be assayed for the presence and/or concentration of an analyte in a sample or specimen, or to determine the presence and/or numbers of one or more components of a sample or specimen, or to make a qualitative assessment of a sample or specimen. A sample can be a fluid sample, such as a liquid sample. Examples of fluid samples that may be assayed include bodily fluids including blood, serum, plasma, saliva, urine, ocular fluid, semen, and spinal fluid; water samples, such as samples of water from oceans, seas, lakes, rivers, and the like, or samples from home, municipal, or industrial water sources, runoff water or sewage samples; and food samples, such as milk or wine. Viscous liquid, semi-solid, or solid specimens may be used to create liquid solutions, eluates,

suspensions, or extracts that can be samples. For example, throat or genital swabs may be suspended in a liquid solution to make a sample. Samples can include a combination of liquids, solids, gasses, or any combination thereof, as, for example a suspension of cells in a buffer or solution. Samples 5 can comprise biological materials, such as cells, microbes, organelles, and biochemical complexes. Liquid samples can be made from solid, semisolid or highly viscous materials, such as soils, fecal matter, tissues, organs, biological fluids or other samples that are not fluid in nature. For example, these solid or semi-solid samples can be mixed with an appropriate solution, 10 such as a buffer, such as a diluent or extraction buffer. The sample can be macerated, frozen and thawed, or otherwise extracted to form a fluid sample. Residual particulates can be removed or reduced using conventional methods, such as filtration or centrifugation.

SPECIMEN COLLECTION AND ANALYSIS SYSTEM

15 Figure 1 is a perspective view of a specimen collection system in an assembled state and Figure 2 is a perspective view of the specimen collection system in an exploded state. The system includes a container 110, a cap 115, a plunger housing 120, a plunger 125, and a test element, such as a test 20 card 130 (the test card 130 is shown in Figure 2). The components of the system are described in detail below.

As described in detail below, the specimen collection system can be used to collect a fluid specimen in the container 110 and to segregate at least a portion of the specimen within a segregation chamber. The segregated portion is easily separated from the remainder of the fluid specimen by

inserting a test element through the cap 115, which breaks a seal and pushes the plunger 125 downward into the container 110. This forces a portion of the fluid specimen to flow into the segregation chamber.

The test element is shown in the form of a test card 130, which can be 5 any type of device that is configured to assay a specimen. The test card has a size and shape that is configured to be inserted into the container 110, as described in detail below. It should be appreciated that the size and shape of the test card 130 can vary.

With reference to Figures 1 and 2, the container 110 generally has a 10 cup-like appearance and includes a base and at least one side wall that extends upwardly from the base so that the container 110 can contain a fluid specimen. An upper rim 128 (shown in Figure 2) of the container 110 defines an opening that can receive fluid. In addition, the upper rim 128 of the container has threads that mate with corresponding threads on the cap 115 15 during coupling of the cap 115 to the container 110. Alternately, other types of mating configurations can be used to couple the cap 115 to the container 110, such as a press-fit configuration or a bayonet configuration.

With reference to Figure 1, the cap 115 has a base 132 and a 20 downwardly-extending flange 134, which has a shape that corresponds to the shape of the rim 128 of the container 110 so that the flange 134 can couple to the rim 128, such as by inserting the flange 134 over the rim 128. In the illustrated embodiment, the base 132 includes a circular depression that can be used as a seat for stacking another container 110 on top of the cap 115. It

should be appreciated, however, that the base 132 can also be flat, as described below in other embodiments.

The inner surface of the flange 134 can have threads (not shown) that mate with the corresponding threads on the rim 128 of the container 110. In 5 this manner, the cap 115 can be coupled to the container 110, such as by rotating the cap 115 on the container 110 so that the threads on the cap 115 couple with the corresponding threads on the rim 128 of the container 110. At least one sealing member, such as an o-ring 210 (shown in Figure 2), can be positioned between the cap 115 and the container 110 to provide a seal 10 therebetween.

With reference to Figures 1 and 2, a test card slot 135 extends through the base 132 of the cap 115. The test card slot 135 is sized to receive the test card 130, as described more fully below. The test card slot 135 generally has a size and shape that corresponds to the size and shape of the test card 15 130 in order to allow for a smooth fit of the test card 130 into the test card slot 135 during use. In the illustrated embodiment, the test card 130 has a flat, rectangular shape. Accordingly, the test card slot 135 has an oblong, rectangular shape that can receive the test card 130 therethrough. It should 20 be appreciated that the test card slot 135 can have other shapes that correspond to differently-shaped test cards 130.

As best shown in Figure 2, a shaft 215 is centrally-located on the cap 115 and is sized to receive at least a portion of the plunger housing 120. The shaft 215 is open at the top and bottom and is enclosed on the sides by a downwardly-extending housing 218 of the cap 115. The housing 218

comprises a set of walls that define a shape that corresponds to the outer shape of the plunger housing 120. In this manner, the shaft 215 can receive the plunger housing 120 when the system is assembled. In the illustrated embodiment, the plunger housing 120 and housing 218 are cylindrical,

5 although they can have other shapes. The test card slot 135 also extends through the housing 218.

As shown in Figures 1 and 2, the shaft 215 is positioned to intersect the test card slot 135 so that a gap is centrally-positioned in the slot. A slot housing 220 (shown in Figure 2) peripherally encloses the test card slot 135.

10 The slot housing 220 extends downwardly from the cap base 132 and outwardly from the housing 218.

The slot housing 220 and an upper region of the plunger housing 120 collectively define an interior fluid segregation chamber 225 (shown in Figure 4) that is described in more detail below. The test card slot 135

15 communicates with the fluid segregation chamber 225 and provides a passageway for introducing the test card 130 into the fluid segregation chamber 225. As described below, the fluid segregation chamber 225 receives at least a portion of the fluid specimen from the container 110 when the plunger 125 is actuated during use.

20 With reference to Figure 2, the plunger housing 120 has an elongated, cylindrical shape. The plunger housing 120 has annular sidewall 121 that provides the plunger housing 120 with a cylindrical shape, although it can also have other shapes. An internal plunger shaft 230 extends vertically through the plunger housing 120. The plunger shaft 230 forms an opening in the

upper end of the plunger housing 120, the opening being sized to receive the plunger 125. The plunger shaft 230 is enclosed at its bottom end by a bottom wall 122 (shown in Figure 3) of the plunger housing 120. At least one fluid entry port 240 comprised of a hole or opening is located on the lower side 5 region of the plunger housing 120.

A pair of opposed test card slots 235 extend through the top end of the plunger housing 120. The test card slots 235 align with the test card slot 135 on the cap 115 when the system is assembled. As shown in Figure 1, the test card slot 135 in the cap 115 and the test card slots 235 in the plunger 10 housing 120 collectively form a single slot that can receive the test card 130 therethrough.

With reference again to Figure 2, the plunger 125 includes an elongate plunging arm 250. A fluid flow lumen 252 extends vertically through the plunging arm 250 such that the fluid flow lumen 252 forms openings through 15 the top and bottom ends of the plunging arm 250. As described below, fluid can flow through the fluid flow lumen from the container 110 and into the fluid segregation chamber 225.

With reference still to Figure 2, a plurality of guide members 255 are positioned in intervals along the length of the plunging arm 250 (the guide 20 members are referred to collectively using the reference numeral 255 and individually using the reference numeral 255 followed by a letter suffix). The guide members 255 comprise protrusions that extend outwardly from the plunging arm 250. At least one of the guide member 255 has a shape and dimension that generally conforms to the cross-sectional shape and

dimension of the internal plunger shaft 230 of the plunger housing 120. In this manner, the plunger 125 can be slidably positioned within the plunger shaft 230, with the guide member(s) 255 acting as guides that permit the plunger 125 to slide upwardly and downwardly in the plunger shaft 230
5 without substantial wobble. The guide members 255 can sealingly engage with the internal walls of the plunger shaft 230 so that the guide members 255 prevent fluid from flowing between the guide members 255 and the internal walls of the plunger shaft 230. In the illustrated embodiment, the plunger 125 includes an upper guide member 255a located at a top end of the plunging arm 250, a middle guide member 255b located at the middle of the plunging arm, 250, and a bottom guide member 255c located at a bottom end of the plunging arm 250. It should be appreciated that the plunger 125 can include more or less guide members 250 and that the guide members 250 can be positioned at various locations and intervals on the plunging arm 250.
10

15 The assembled specimen collection system is now described in more detail with reference to Figures 3 and 4. Figure 3 is a cross-sectional view of the assembled system along line 3-3 of Figure 1 and Figure 4 is a cross-sectional view of the assembled system along line 4-4 of Figure 1. With reference to Figure 3, in the assembled state, the cap 115 is coupled to the top of the container 110. As mentioned, the cap 115 and container 110 both have threads that mate to allow the cap 115 to be screwed onto the container 110. One or more o-rings can be positioned between the cap 115 and container 110 for providing a seal. It should be appreciated that other mating means can be used to couple the cap 115 to the container 110.
20

With reference to Figure 3, when the system is assembled, the plunger housing 120 is concentrically positioned within the housing 218 such that the housing 218 surrounds at least a portion of the plunger housing 120. The top end of the plunger housing 120 is supported by the cap 115 and the remainder of the plunger housing 120 extends downwardly into the container 110. In this regard, the top end of the plunger housing 120 has a lip 310 that is positioned within a correspondingly-shaped seat 315 in the cap 115 to provide a smooth fit between the cap 115 and the plunger housing 120.

Alternately, the plunger housing 120 can be integrally formed with the cap 115, as described below in other embodiments. It should be appreciated that various components of the fluid collection system can be integrally formed as single or plural pieces according to design and manufacturing criteria.

In one embodiment, the plunger housing 120 is sized such that the fluid entry ports 240 are located in a bottom region of the container 110 when the plunger housing 120 is positioned in the shaft 215. This increases the likelihood that fluid specimen in the container 110 will flow into the entry ports 240. However, it should be appreciated that the location of the fluid entry ports 240 can vary.

With reference to Figure 3, the plunger 125 is slidably positioned within the plunger shaft 230 of the plunger housing 120. As mentioned, the sizes and shapes of the guide members 255 correspond to the size and shape of the plunger shaft 230 in the plunger housing 120. In this manner, the plunger 125 can be slidably and securely positioned within the plunger shaft 230 with the peripheral edges of the guide members 255 abutting the internal walls of

the plunger shaft 230. When positioned as such, the plunging arm 255 coaxially aligns with a vertical axis 317 of the plunger shaft 230.

As shown in Figure 4, the plunger 125 has a length L that is shorter than the length L1 of the plunger shaft 230. Accordingly, the relative lengths 5 provide additional space within the plunger shaft 230 so that the plunger 125 can slide in both an upward and downward direction within the plunger shaft 230 of the plunger housing 120.

In an initial state, which is shown in Figure 3, the plunger 125 is positioned such that the top end of the plunger 125 is located at or near the 10 top of the plunger housing 120. As mentioned, the plunger 125 has a length L that is smaller than the length L1 of the plunger shaft 230. The relative lengths of L and L1 are such that when the plunger 125 is in the initial state, the bottom end of the plunger 125 is located above the fluid entry ports 240 of the plunger housing 120. In addition, the relative lengths of L and L1 are 15 such that a reservoir chamber 318 is formed within the lower end of the plunger shaft 230. The guide member 255c on the lower end of the plunger 120 defines the upper end of the reservoir chamber 318. The internal side wall(s) of the plunger housing 120 define the sides of the reservoir chamber 318, and the internal bottom wall 122 of the plunger housing 120 defines the 20 lower end of the reservoir chamber 318.

The fluid flow lumen 252 forms a first opening in the upper end of the plunger 125, wherein the first opening opens into the fluid segregation chamber 225 when the plunger is moved downward, as described below.

The fluid flow lumen 252 communicates with the reservoir chamber 318 via a

second opening in the bottom end of the plunger 125. The second opening provides a passageway for fluid to flow into the fluid flow lumen 252 from the reservoir chamber 318. The plunger 125 can move in a downward direction through the reservoir chamber 318 during actuation of the plunger in order to 5 cause fluid to flow into the fluid flow lumen 252, as described more fully below.

As shown in Figure 3, a seal member 320 is located on the top of the plunger 125. The seal member 320 entirely covers the upper, open end of the fluid flow lumen 252 so as to prevent fluid from flowing out the fluid flow 10 lumen into the segregation chamber 225. In one embodiment, the seal member 320 is a strip or band of adhesive material that is sized and shaped to entirely cover the upper opening in the fluid flow lumen 252. The seal member 320 is made of a material that can be punctured when a sufficient amount of pressure is applied to the seal member 320.

15 As discussed above, at least a portion of the cap 115 forms a fluid segregation chamber 225 that communicates with the test card slot 135. This is shown in more detail in Figure 4. The fluid segregation chamber 225 is a chamber that is contained within the slot housing 220 and the plunger housing 120. As described below, at least a portion of the test card 130 can 20 be inserted into the fluid segregation chamber 225 by inserting the test card 130 through the slot 135 in the cap 115 and the slot 235 in the plunger housing 120. Toward this end, a bottom portion of the test card 130 includes a structure that can break or puncture the seal member when the test card 130 is inserted through the slots. For example, in the embodiment shown in

Figure 2, the test card 130 includes a puncture device comprised of a sharp protrusion 155 that can be used to puncture the seal member 320.

The use of the specimen collection system is now described with reference to Figures 5-10. In an initial step, a fluid specimen is first collected 5 in the container 110. This can be accomplished, for example, by providing the container 110 and the detached cap 115 to a subject that will provide the biological specimen. The subject then collects the fluid specimen in the container 110, such as, for example, by urinating into the container 110. It should be appreciated that specimen can be provided in other manners. The 10 cap 115 is then coupled to the container, such as by screwing the cap 115 onto the container 110 or by using some other mechanism. The capped container 110 thus contains a fluid specimen 510, as shown in Figure 5. The specimen 510 resides in a main chamber 512 of the container 110, wherein the main chamber 512 is separated from the segregation chamber 225 15 (shown in Figure 7) of the container 110. At least a portion of the specimen 510 flows through the entry ports 240 into the reservoir chamber 318, as exhibited by the arrows labeled 514 in Figure 5.

At this stage of the procedure, the specimen 510 in the reservoir chamber 318 will not flow into the fluid flow lumen 252, as the fluid flow lumen 20 252 contains air and is sealed or closed at the upper end by the seal member 320. In addition, the bottom guide member 255c forms a seal with the internal walls of the plunger housing 120 to prevent any fluid from flowing between the guide member 255c and the internal walls of the plunger housing 120. Thus, the bottom guide member 255c prevents the specimen from

flowing upwardly through the plunger housing 120 past the bottom guide member 255c. Even if some fluid specimen should flow into the fluid flow lumen 252, the seal member 320 covers the upper end of the specimen 510 and prevents the specimen 510 from flowing into the segregation chamber

5 225.

With reference to Figures 6 and 7, the test card 130 is next inserted into the test card slot in the cap 115. The test card 130 is moved downward such that the protrusion 155 on the bottom end of the test card 130 breaks through the seal member 320, such as by puncturing a hole in the seal member 320. This broken seal 320 provides an opening between the upper end of the fluid flow lumen 252 and the segregation chamber 225. As best shown in Figure 7, the bottom portion of the test card 130 now protrudes into the segregation chamber 225 through the test card slot. At this stage of the operation, the segregation chamber 225 is empty. That is, the segregation

10 chamber does not contain any of the specimen 510.

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As shown in Figure 7, a bottom edge of the test card 130 abuts an upper edge of the plunger 125. More specifically, the bottom edge of the test card 130 abuts the upper guide member 255a, although the test card 130 can abut other portions of the plunger 125. When the test card 130 is positioned relative to the plunger 125 as such, the test card 130 can be used to push the plunger 125 in a downward direction through the plunger housing 120.

20

With reference to Figure 8, a user next pushes the test card 130 in a downward direction. Because the test card 130 abuts the upper end of the plunger 125, the test card 130 pushes the plunger 125 in a downward

direction as the test card 130 moves downward. The bottom guide member 255c of the plunger 125 thus travels downwardly through the reservoir chamber 318 and reduces the volume of the reservoir chamber 318. As it moves downward through the reservoir chamber, the bottom guide member 255c displaces the fluid in the reservoir chamber 318.

5 While this occurs, the bottom guide member 255c travels downward past the fluid entry ports 240, as shown in Figure 8. As mentioned, the bottom guide member 255c has a sealing engagement with the internal wall of the plunger shaft 230 so that the guide member 255c blocks the specimen 10 510 from flowing into the fluid entry ports 240. Thus, the fluid specimen 510 in the reservoir chamber 318 is prevented from exiting the reservoir chamber 318 through the fluid entry ports 240. As the volume of the reservoir chamber 318 decreases due to the downward movement of the plunger 125, the fluid specimen 510 is forced to travel upward into the fluid flow lumen 252 through 15 the hole in the bottom end of the plunger 125, as represented by the arrow 810 in Figure 8. As mentioned, the seal member 320 was previously punctured, which opened the upper end of the fluid flow lumen 252, thereby allowing any air in the fluid flow lumen 252 to escape as the fluid specimen flows into the fluid flow lumen 252.

20 As shown in Figures 9 and 10, the portion 910 of the fluid specimen 510 that was in the reservoir chamber 318 continues to flow upward through the fluid flow lumen 252 as the plunger 125 moves downward. Eventually, the portion 910 of the fluid specimen 510 flows into the segregation chamber 225 through the upper, open end of the fluid flow lumen 252. Thus, the

portion 910 of the fluid specimen 510 fills at least a portion of the segregation chamber 225, as shown in Figures 9 and 10. While the foregoing has occurred, the test card 130 has moved downward so that at least a portion of the test card 130 is also positioned within the segregation chamber 225. In 5 this manner, the test card 130 is exposed to the fluid specimen contained in the segregation chamber 225.

There is now described a second embodiment of the specimen collection system. Unless otherwise noted, like numerals refer to like parts. With reference to Figures 11 and 12, the second embodiment includes the 10 container 110 and the cap 135. The slot 135 is located directly in the cap 115.

As best shown in Figure 12, a seal 1210 can be removably positioned on the cap 115 so as to sealingly cover the slot 135. The seal 1210 can be manufactured of a flexible material. A bottom gasket 1205 is located on the 15 cap directly below the slot 135.

With reference still to Figure 12, a plunger housing 1210 includes a cap interface 1211 that has a shape that can engage the bottom of the cap 115. In the illustrated embodiment, the cap interface 1211 has a circular, disk-like shape that conforms to the shape of the bottom of the cap 115 to 20 allow the cap interface to smoothly engage the cap 115. It should be appreciated that the cap interface 1211 can have other shapes.

The plunger housing 1210 further includes a chamber housing 1217 that at least partially or entirely encloses the internal segregation chamber 225 into which the test card 130 can be inserted via the slot 135. In this

regard, a corresponding slot 1218 is located in the cap interface 1211 for receiving test card 130.

The plunger housing 1210 also includes cylindrical portion 1212 that extends downwardly from the cap interface 1211. The cylindrical portion 1212 defines the internal plunger shaft 230 in which the plunger 125 can movably slide, as described in the previous embodiment. At least one fluid entry port 240 is located on the cylindrical portion 1212 to provide fluid access to the plunger shaft 230.

With reference still to Figure 12, a cylindrical guide 1215 is dimensioned to be slidably positioned within the plunger shaft 230. The cylindrical guide 1215 has an internal lumen that slidably receives an upper region of the plunger 125. The cylindrical guide 1215 includes one or more detents, such as circular ridges 1225, that engage corresponding guide members 255 on the plunger 125 for securing position of the plunger 125 in the guide 1215.

Figure 13 shows a cross-sectional, perspective view of the specimen collection system in an assembled state, with the plunger 125 in an initial position. The guide members 255 are engaged with the ridges 1225 to retain the plunger 125 in the initial position, which is elevated above a puncture device comprised of a sharp-edged protrusion 1310 that extends upwardly from the bottom of the container 110. A seal member 1315 is positioned on the bottom end of the plunger 125 so as to sealingly cover the hole formed by the bottom end of the fluid flow lumen 252 that extends through the plunger 125.

As shown in Figure 14, the plunger 125 can be forced into a secondary position wherein the plunger 125 has been moved downward such that the protrusion 1310 punctured the seal member 1315. The plunger 125 is moved to the secondary position by inserting the test card 130 into the slot 135 and 5 pushing the test card 130 downward. This causes the bottom end of the test card 130 to abut the upper end of the plunger 125, thereby sliding the plunger 125 and the guide 1215 downwardly through the plunger shaft 230. The protrusion 1310 is now positioned within the fluid flow lumen 252. It should be appreciated that the protrusion 1310 can take on other forms and 10 structures that are configured to puncture the seal member 1315 when the plunger 125 is moved downward.

With reference to Figures 15-17, the operation of the specimen collection system is now further described. As shown in Figure 15, the specimen 510 resides in a main chamber 512 of the container 110, wherein 15 the main chamber 512 is separated from the segregation chamber 225 (shown in Figure 7) of the container 110. The upper end of the fluid flow lumen 252 can be covered by a seal member 320 and the lower end can also be covered by a seal member (as was shown in Figure 13).

As shown in Figure 16, at least a portion of the specimen 510 flows 20 through the entry ports 240 into the reservoir chamber 318. The test card 130 is inserted into the slot 135 in the cap 115 such that the lower end of the test card abuts the upper end of the plunger 125. With reference to Figure 17, a user then pushes the test card 130 downward through the slot 135, which forces the plunger downwardly through the plunger shaft 230. The test card

130 can puncture the seal member 320 on the top end of the plunger 125. Alternatively, or in concert with the puncturing of the seal member 320, the protrusion 1310 can puncture the lower seal member 1315, if present, as the plunger 125 moves downward. The openings into the fluid flow lumen 252
5 are thereby unsealed so that the specimen in the reservoir chamber 318 can flow upwardly into the fluid flow lumen 252 and into the segregation chamber 225. As described above with respect to the previous embodiment, the test card 130 has moved downward so that at least a portion of the test card 130 is also positioned within the segregation chamber 225. In this manner, the
10 test card 130 is exposed to the fluid specimen contained in the segregation chamber 225.

Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof
15 are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.

CLAIMS

What is claimed:

1. A device for collecting a fluid specimen, comprising:
 - a container that can receive a fluid specimen;
 - a plunger movably positioned within the container, wherein the plunger can move from an initial position at an upper region of the container to a secondary position below the first position;
 - a fluid segregation chamber that can receive a portion of the fluid specimen from the container, wherein any fluid in the segregation chamber is segregated from the fluid specimen in the container;
 - a fluid flow lumen that provides a passageway for at least a portion of the fluid specimen to flow into the fluid segregation chamber, wherein a first end of the passageway has a first opening that opens into the fluid segregation chamber and a second end of the passageway has a second opening that can receive at least a portion of the fluid specimen; and
 - a seal member that covers the first opening or the second opening to prevent fluid from flowing therethrough;
- wherein a test element can be used to push the plunger from the initial position toward the secondary position to break the seal member and cause at least a portion of the fluid specimen to flow through the second opening into the fluid flow lumen and into the fluid segregation chamber through the first opening.

2. The device of claim 1, additionally comprising a cap that couples to the container.
3. The device of claim 1, additionally comprising a slot extending through the cap and communicating with the fluid segregation chamber, the slot sized to receive the test element therethrough, and wherein the test element can be inserted into the slot to break the seal member and push the plunger from the initial position toward the secondary position, and wherein at least a portion of the test element moves into the fluid segregation chamber as the test element pushes the plunger from the initial position toward the secondary position.
4. The device of claim 2, additionally comprising a plunger housing that extends downwardly from the cap into the container, the plunger housing including sidewalls and a bottom wall, and wherein a plunger shaft is located within the plunger housing, the plunger being slidably positioned in the plunger shaft.
5. The device of claim 4, wherein a reservoir chamber is positioned in a lower region of the plunger housing beneath the plunger, and wherein at least one fluid entry port is located in the side wall of the plunger housing so as to communicate with the reservoir chamber, the fluid entry port providing a pathway through which at least a portion of the fluid specimen can flow into the reservoir chamber from the container.

6. The device of claim 5, wherein the second opening of the fluid flow lumen opens into the reservoir chamber, and wherein at least a portion of the plunger blocks fluid from flowing into the fluid entry port when the plunger moves from the initial position toward the secondary position such that fluid in the reservoir must flow into the fluid flow lumen as the plunger moves toward the second position.

7. The device of claim 1, wherein the fluid flow lumen is located within the plunger.

8. The device of claim 4, wherein the plunger housing is removably attached to the cap.

9. A method of analyzing a fluid specimen, comprising:
providing a container that contains the fluid specimen, the container including a fluid segregation chamber that can segregate at least a first portion of the fluid specimen from a second portion of the fluid specimen, wherein a fluid flow lumen provides a fluid passageway for a portion of the fluid specimen to flow from the container into the fluid segregation chamber, the fluid flow lumen having a seal that prevents fluid from flowing into the fluid flow lumen;

inserting a test element into the container so that the seal is punctured and the test element depresses a plunger to cause at least a portion of fluid in

the container to flow into the fluid flow lumen and into the fluid segregation chamber, wherein at least a portion of the test element moves into the fluid segregation chamber in contact with the portion of the fluid specimen in the fluid segregation chamber.

10. The method of claim 9, additionally comprising coupling a cap onto the container, wherein the cap is coupled to a plunger housing that defines a plunger shaft in which the plunger is movably positioned.

11. The method of claim 10, wherein at least a portion of the fluid specimen flows into a reservoir chamber in a bottom region of the plunger housing when the cap is coupled to the container, and wherein the plunger decreases the volume of the reservoir chamber as the plunger is depressed to thereby force the portion of the fluid specimen in the reservoir chamber to flow into the fluid flow lumen.

12. The method of claim 11, wherein the portion of the fluid specimen flows into the reservoir chamber through at least one fluid entry port in the plunger housing, and wherein the plunger blocks the portion of the fluid specimen from flowing out of the reservoir chamber through the fluid entry port as the plunger is depressed.

13. The method of claim 10, wherein inserting the test element into the container comprises inserting the test element through a slot in the cap.

14. A device for collecting a fluid specimen, comprising:
- a container that defines a main chamber that can receive a fluid specimen;
- a fluid segregation chamber coupled to the container for segregating at least a portion of the fluid specimen from the main chamber;
- a fluid flow lumen that provides a passageway for fluid to flow into the fluid segregation chamber from the main chamber, the fluid flow lumen having an upper opening that opens into the segregation chamber;
- a seal that covers the upper opening of the fluid flow lumen to prevent fluid from flowing through the upper opening; and
- a plunger coupled to the container, wherein the plunger can be moved in a downward direction to force at least a portion of the fluid specimen to flow into the fluid flow lumen toward the fluid segregation chamber, wherein the seal must be broken in order for the plunger to be moved in a downward direction.

15. The device of claim 14, additionally comprising a cap that couples to the container, wherein the cap includes a plunger housing that extends downwardly into the container when the cap is coupled to the container, and wherein the plunger is movably positioned in a shaft in the plunger housing.

16. The device of claim 14, wherein a lower region of the plunger housing forms a reservoir chamber, and wherein the fluid specimen in the main chamber flows into the reservoir chamber through a fluid entry port in the plunger housing when the cap is coupled to the container.

17. The device of claim 16, wherein the fluid flow lumen has a lower opening that opens into the reservoir chamber and wherein the plunger blocks fluid in the reservoir chamber from flowing through the fluid entry port as the plunger moves downward, and wherein, as the plunger moves downward, the plunger displaces the fluid specimen in the reservoir chamber to cause the fluid in the reservoir chamber to flow into the fluid flow lumen toward the segregation chamber.

18. The device of claim 14, wherein a test element can be inserted into the container such that the test element breaks the seal and moves the plunger in a downward direction.

19. The device of claim 14, wherein the fluid flow lumen is positioned inside the plunger.

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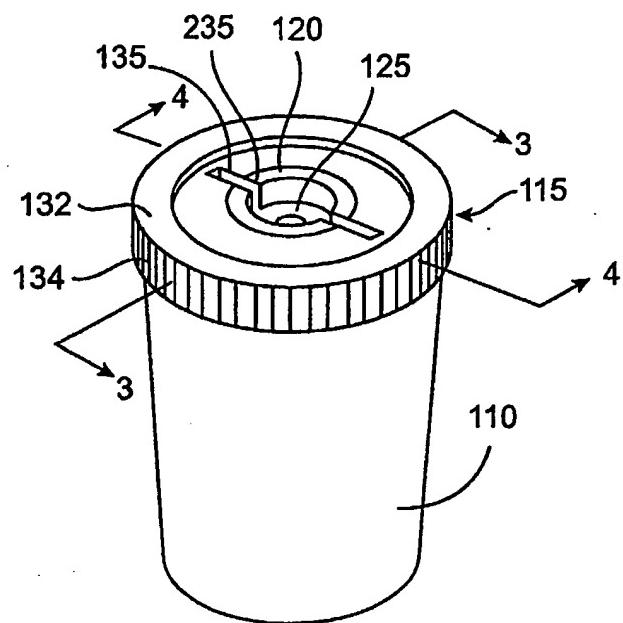


FIG. 1

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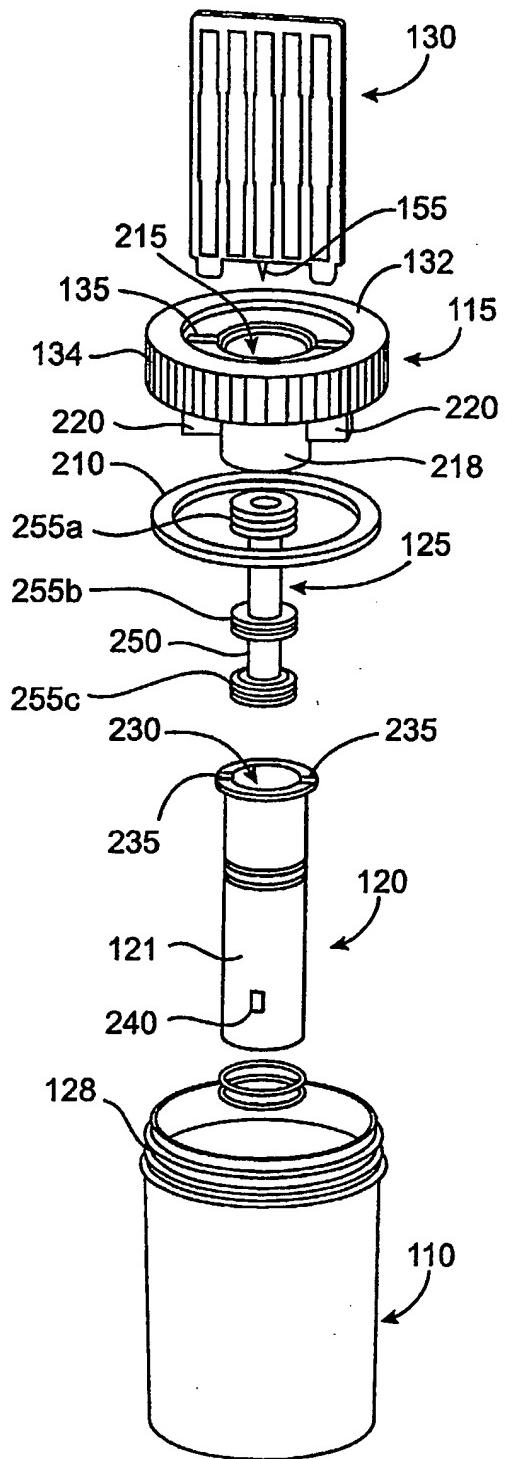


FIG. 2

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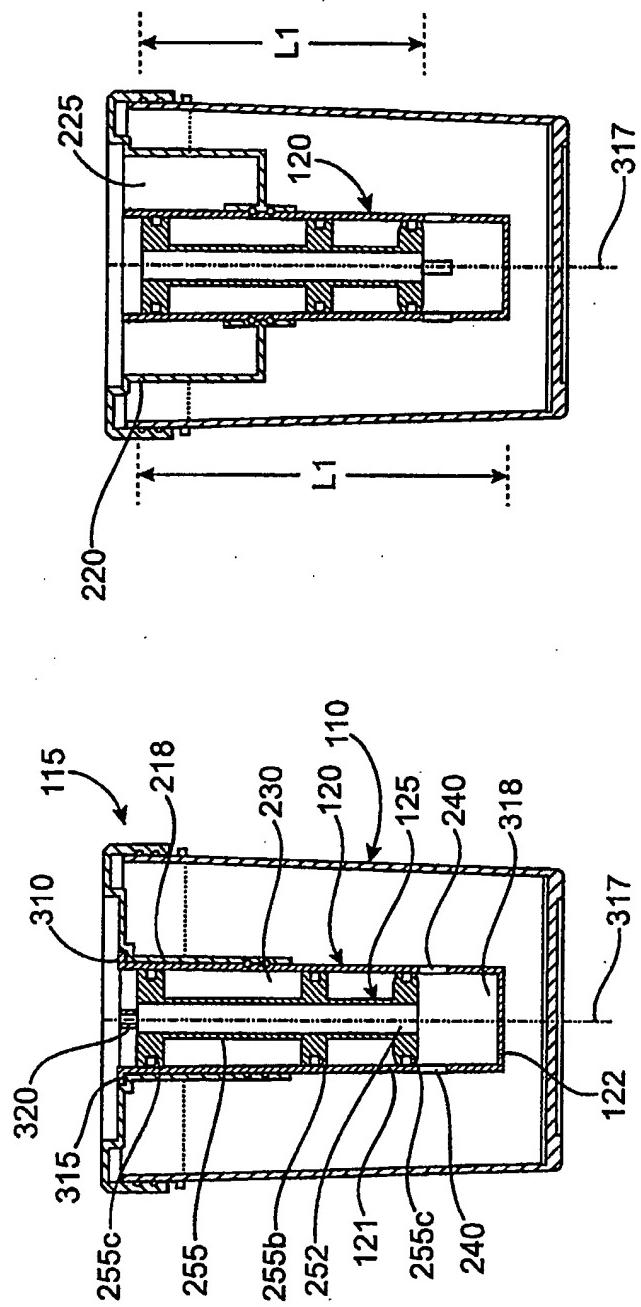


FIG. 3

FIG. 4

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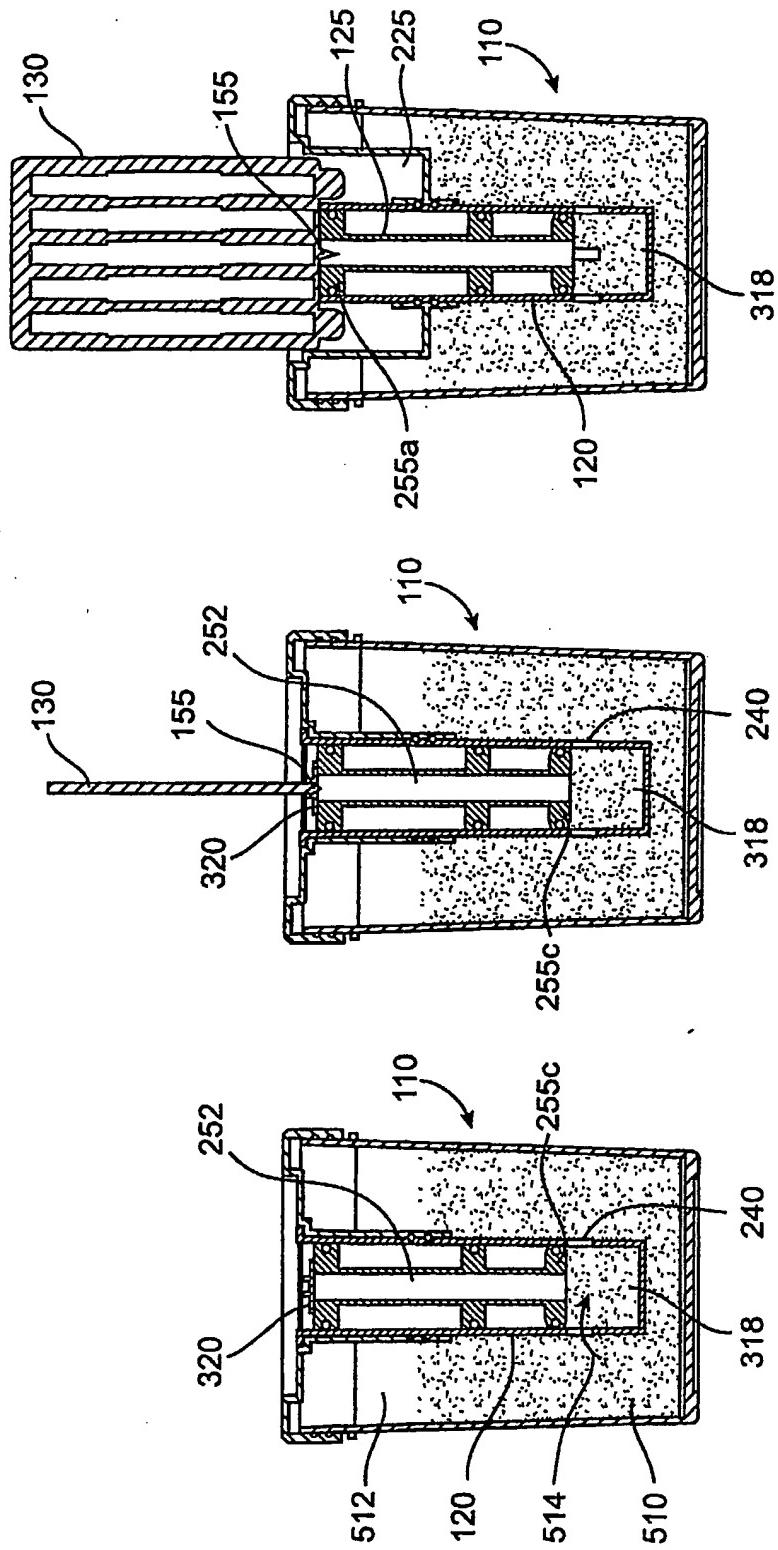


FIG. 5

FIG. 6

FIG. 7

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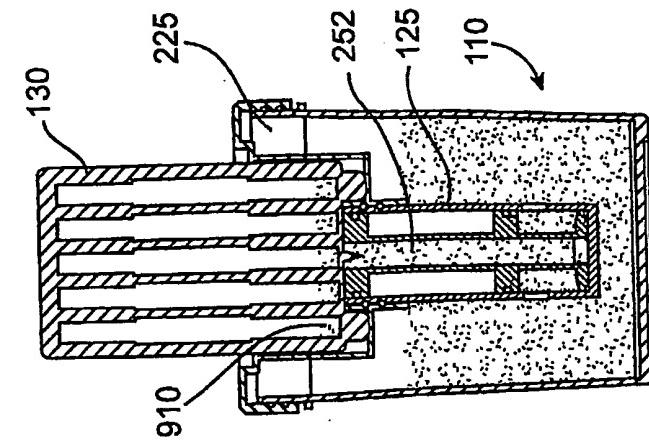


FIG. 10

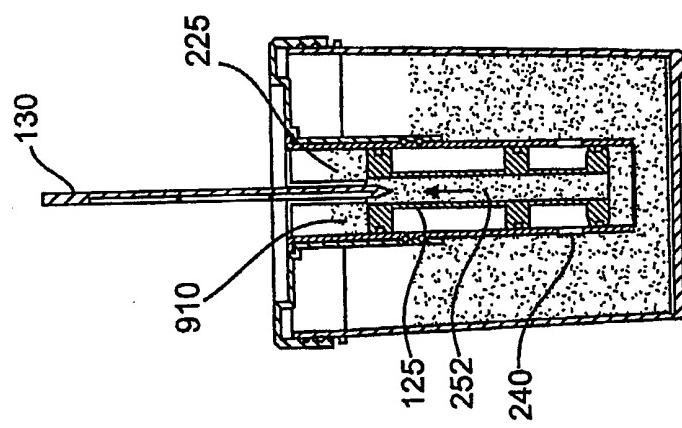


FIG. 9

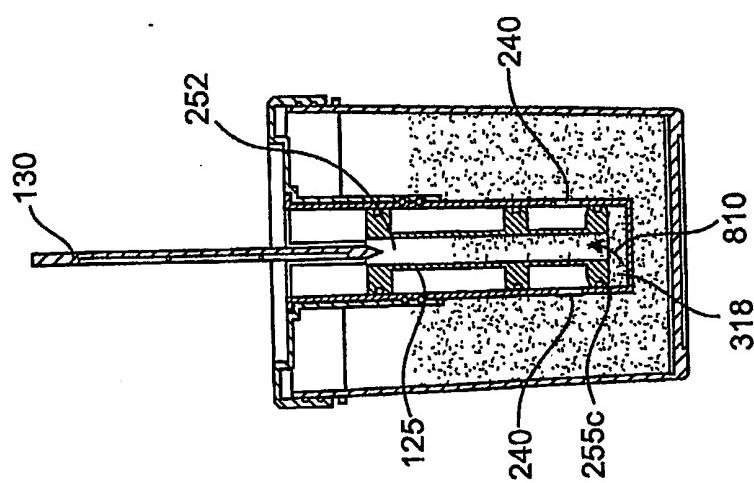


FIG. 8

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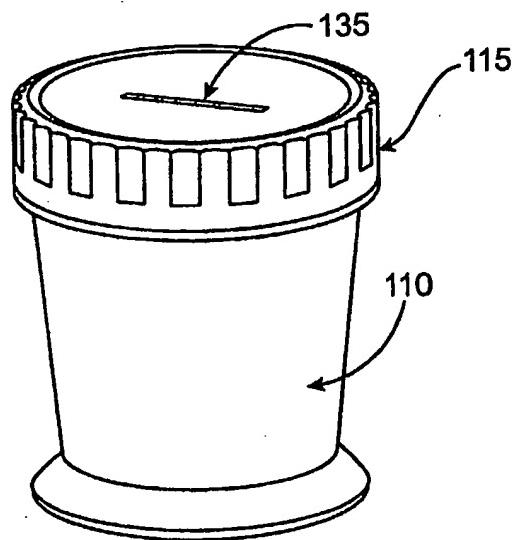


FIG. 11

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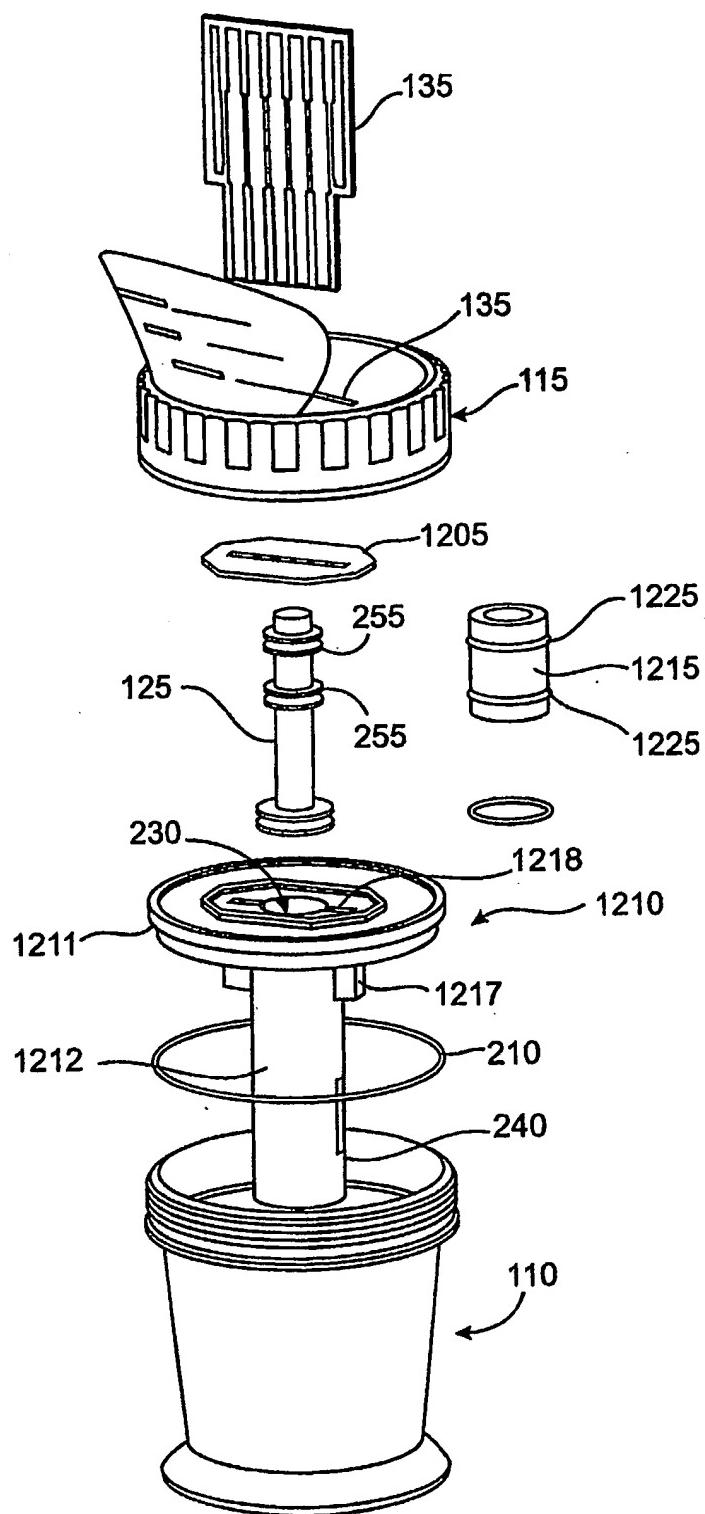


FIG. 12

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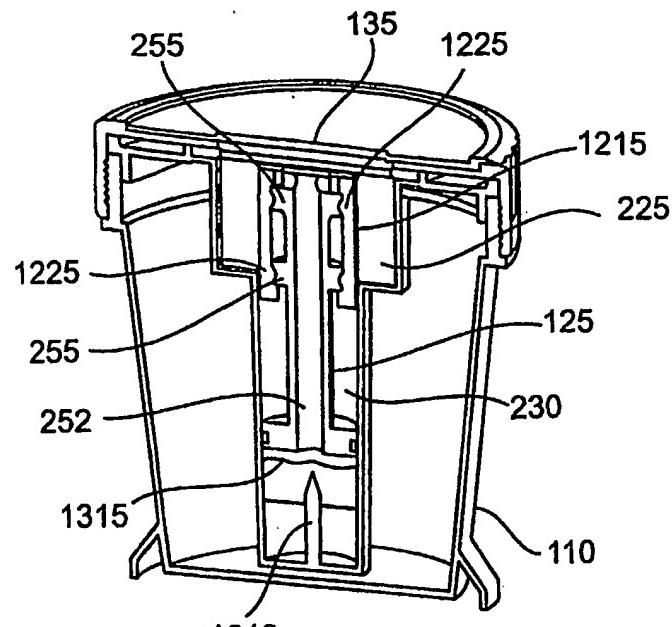


FIG. 13

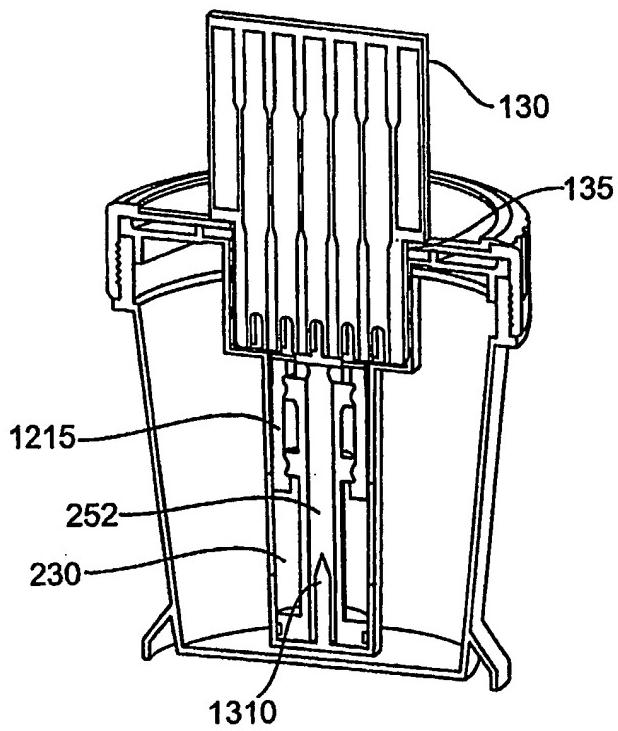


FIG. 14

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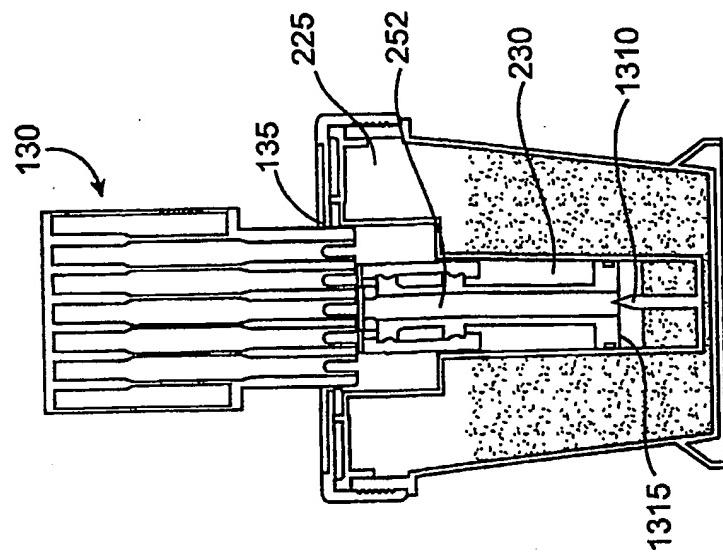


FIG. 17

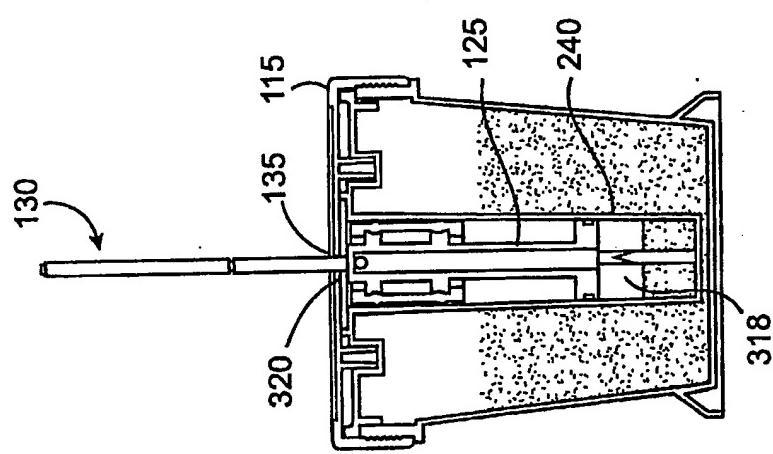


FIG. 16

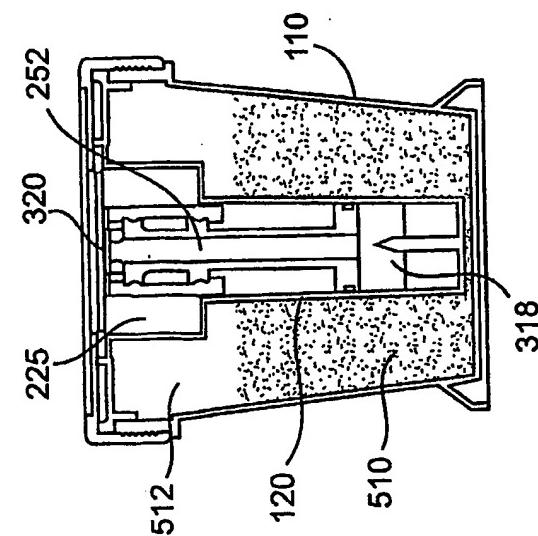


FIG. 15

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